K130840

**OSSTEM Implant Co., Ltd.**
#507-8 Geoje3-Dong Yeonje-Gu Busan, 611-804 Republic of Korea
Tel: +82 51 850-2500 Fax: +82 51 850-4341 www.osstem.com

# 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: February 26, 2013

1. Company and Correspondent making the submission:

| | |
|---|---|
| - Submitter's Name : | OSSTEM Implant Co., Ltd. |
| - Address : | #507-8 Geoje3-Dong Yeonje-Gu<br>Busan, 611-804, Republic of Korea |
| - Contact : | Mr. Hee Kwon Son |
| - Phone: | +82 51 850 2575 |

2. Device :

SEP 18 2013

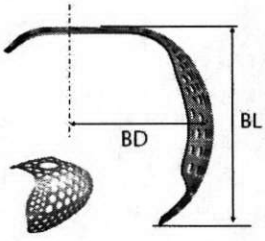
| | |
|---|---|
| Trade or (Proprietary) Name : | SMARTbuilder System (SB1) |
| Classification Name : | Bone Plate<br>21CFR872.4760<br>Class II<br>JEY |

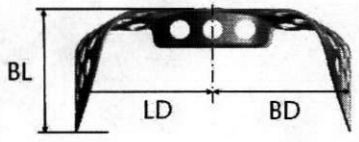
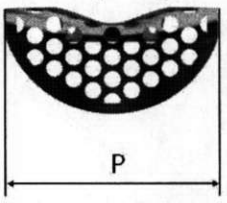
3. Predicate Device:

The SMARTbuilder System, OSSTEM IMPLANT Co., Ltd., K120951

4. Description:

Customized 3D Pre-Formed Titanium Membrane. SMARTbuilder System (SB1) is the non-absorbable membrane that is made of titanium metal to stabilize and support of bone graft after bone transplantation at the area having autogenous bone deficiency in the oral cavity.

| | | Dimensions (mm) |
|---|---|---|
|  |  | SMARTbuilder SB2<br><br>P(Proximal): 5.0, 6.0, 7.0<br>BW(Buccal width): 9.0, 12.0<br>BD(Buccal Distance): 5.5<br>BL(Buccal Length): 7, 9 |

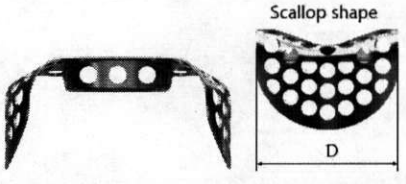
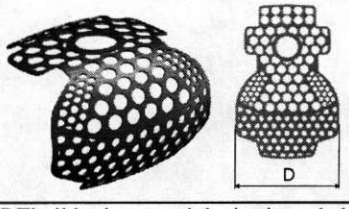
| | | |
|---|---|---|
|  | Scallop shape<br>  | SMARTbuilder SB1<br><br>P(Proximal): 7.0, 10.0, 12.0<br>LD(Lingual Dixtance): 5.0, 5.5, 6.5<br>BD(Buccal Distance): 5.0, 5.5, 6.5<br>BL(Buccal Length): 3.0, 5.0 |

The SMARTbuilder System (SB1) is made of pure titanium metal and supplied sterile.

The SMARTbuilder System (SB1) is used with GS3 System (K091208) of OSSTEM Implant Co., Ltd. and US.SS.GS System (K073247) of OSSTEM Implant Co., Ltd.

The SMARTbuilder is substantially equivalent in design, function and intended use to the SMARTbuilder System, SMARTbuilder (K120951) of OSSTEM Implant Co., Ltd.

**- Substantial Equivalence Matrix**

| | Proposed Device | Predicate devices |
|---|---|---|
| | SMARTbuilder (SB1) | SMARTbuilder (SB2) |
| **510(K)** | - | K120951 |
| **Design** |  |  |
| **Intended use** | SMARTbuilder is a metal device intended for use with a dental implant to stabilize and support of bone graft in dento-alveolar bony defect sites. | SMARTbuilder is a metal device intended for use with a dental implant to stabilize and support of bone graft in dento-alveolar bony defect sites. |
| **Material of Fixture** | Pure Titanium Grade 2 (ASTM F67) | Pure Titanium Grade 2 (ASTM F67) |
| **Width (D)** | 7, 10, 12 | 8, 9, 10, 12 |
| **Sterilization** | Sterilie | Sterilie |
| **Shelf life** | 8years | 5years |
| **S E** | The SMARTbuilder has same material and indication for use and similar design and technological characteristics as the predicate device, such as the SMARTbuilder System | |

5. Indication for use :
   The SMARTbuilder System (SB1) is a metal device intended for use with a dental implant to stabilize and support of bone graft in dento-alveolar bony defect sites.

6. Review :
   The SMARTbuilder System (SB1) has the same material and indication for use and similar design and technological characteristics as the predicate device.

7. Summary of nonclinical testing
   Biocompatibility evaluation for SMARTbuilder System is not considered because SMARTbuilder System (SB1) has same material and manufacture process with SMARTbuilder System, predicate device and SMARTbuilder System (SB1) material, Pure Titanium Grade 2 (ASTM F67) has been generally and widely used as a dental material such as implant for a long time

8. Summary of clinical testing
   No clinical studies are submitted

9. Conclusion :
   Based on the information provided in this premarket notification Osstem Implant Co., Ltd. concludes that the SMARTbuilder system (SB1) is substantially equivalent to the predicate devices as described herein

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 18, 2013

OSSTEM Implant Company, Limited
C/O Mr. Patrick Lim
Manager
HIOSSEN Incorporated
85 Ben Fairless Drive
Fairless Hills, Pennsylvania 19030

Re: K130840
Trade/Device Name: SMARTbuilder System (SB1)
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: August 9, 2013
Received: August 20, 2013

Dear Mr. Lim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,


Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

OSSTEM IMPLANT
**OSSTEM Implant Co., Ltd.**
#507-8 Geoje3-Dong Yeonje-Gu Busan, 611-804 Republic of Korea
Tel: +82 51 850-2500 Fax: +82 51 850-4341 www.osstem.com

510(k) Number K 130840

Device Name : SMARTbuilder system (SB1)

Indication for use : SMARTbuilder System is a metal (Non-resorbable membrane) device intended for use with a dental implant to stabilize and support of bone graft in dento-alveolar bony defect sites.

Prescription Use X (Per 21CFR801 Subpart D) OR Over-The-Counter Use _____. (Per 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen -S
2013.09.18 08:38:56 -04'00'

Division Sign-Off)
vision of Anesthesiology, General Hospital
ction Control, Dental Devices

510(k) Number: K130840